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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/586,298

04/17/2007

Jaime Gosalvez Berenguer

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT

PAPER NUMBER

1637

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/586,298	Applicant(s) GOSALVEZ BERENGUER ET AL.	
	Examiner Suryaprabha Chunduru	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-34 is/are pending in the application.
- 4a) Of the above claim(s) 31-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Applicants' response to the office action field on January 02, 2009 has been considered and acknowledged.

Status of the application and response to arguments

2. Claims 1-17 were cancelled. New claims 18-34 were added. New claims 18-30 are considered for examination that read on previously examined claims 1-13, 16-17. New claims 31-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group. Applicants' arguments and the amendment have been fully considered and deemed persuasive. All the objections and rejections that are not reiterated herein are withdrawn in view of the amendment and persuasive arguments. Applicants' arguments regarding the rejoinder of kit claims were fully considered, and the rejoinder of claims would be considered at the time of the allowance. The restriction requirement is deemed proper and made FINAL.

Objection to claimed foreign priority

3. This application filed on April 17, 2007 is a 371 of PCT/IB05/00187 filed on 1/26/2005 which claims foreign priority to SPAIN P20040163 filed on 01/26/2004.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in SPAIN P20040163 on 01/26/2004. It is noted, however, that applicant has not filed a certified copy of the foreign application as required by 35 U.S.C. 119(b).

Informalities

4. The following informalities were noted:

(i) the claim 18 recites 'method to', it should have been 'A method to'.

(ii) the dependent claims 19-29 recite 'method according to claim'. It should have been 'the method according to claim'.

(iii) in claim 18 'chromatin or DNA' is suggested in place of 'chromatin/DNA'.

Appropriate correction is required.

Objections to the Specification

5. The disclosure is objected to because of the following informalities:

(i) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see page 30, line 18). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 18-21, 27, 29 rejected under 35 U.S.C. 102(b) as being anticipated by Spano et al. (Molecular Human Reproduction, Vol. 5, No. 1, pp. 29-37, 1999).

Spano et al. teach a method of claims 18-19 to evaluate the integrity of chromatin DNA or DNA of sperm cells of an animal (human) comprising

(a) treating a sample containing the sperm, with a DNA denaturing solution (See page 30, col. 2, line 8-9 of paragraph under the sub heading flow cytometric analysis of SCSA);

(b) a single step treatment of the sample in solution obtained in step a) with a lysis solution to extract nuclear proteins of the sperm cells, wherein the lysis solution does not comprise protein denaturing detergents (see page 30, col. 2, line 9-12 of paragraph under the sub heading flow cytometric analysis of SCSA);

(c) evaluating the integrity of the chromatin/DNA of the sperm cells based on measurement of halo of the size of the sperm cells (see page 30, paragraph under the sub heading flow cytometric analysis of SCSA, page 31, col. 2, paragraph under flow cytometry sub title).

With regard to claims 20-21, Spano et al. teach that the lysis solution comprises non-ionic non protein detergent as Triton X-100 (see page 30, col. 2, line 9-12 of paragraph under the sub heading flow cytometric analysis of SCSA).

With regard to claim 27, Spano et al. teach that after the step a) and b) there is a staining step (see page 30, col. 2, line 12-15 of paragraph under the sub heading flow cytometric analysis of SCSA).

With regard to claim 29, Spano et al. teach that the sample containing the sperm is included in a medium similar to a suspension (see page 30, col. 2, line 1-8 of paragraph under the sub heading flow cytometric analysis of SCSA). Accordingly the claims are anticipated.

B. Claims 18-21, 24-27, 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Januskauskas et al. (Theriogenology, Vol. 55, pp. 947-961, 2001).

Januskauskas et al. teach a method of claims 18-19 to evaluate the integrity of chromatin DNA or DNA of sperm cells of an animal (human) comprising

(a) treating a sample containing the sperm, with a DNA denaturing solution (low-pH acid solution, (0.08N HCl) see page 951, line 7-8 of paragraph under the sub heading sperm staining with Acridine orange);

(b) a single step treatment of the sample in solution obtained in step a) with a lysis solution (lysis solution with Triton X-100) to extract nuclear proteins of the sperm cells, wherein the lysis solution does not comprise protein denaturing detergents see page 951, line 7-8 of paragraph under the sub heading sperm staining with Acridine orange);

(c) evaluating the integrity of the chromatin/DNA of the sperm cells based on measurement of halo of the size of the sperm cells see page 951, paragraph under flow cytometry analysis).

With regard to claims 20-21, Januskauskas et al. teach that the lysis solution comprises non-ionic non protein detergent as Triton X-100 (see page 951, line 7-8 of paragraph under the sub heading sperm staining with Acridine orange).

With regard to claim 24-26, Januskauskas et al. teach that the denaturing solution contains hydrochloric acid (see page 951, line 7-8 of paragraph under the sub heading sperm staining with Acridine orange);

With regard to claim 27, Januskauskas et al. teach that after the step a) and b) there is a staining step see page 951, line 8-10 of paragraph under the sub heading sperm staining with Acridine orange);

With regard to claim 29, Januskauskas et al. teach that the sample containing the sperm is included in a medium similar to a suspension see page 951, line 1-7 of paragraph under the sub heading sperm staining with Acridine orange). Accordingly the claims are anticipated.

C. Claims 18, 20-23, 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Connell et al. (Fertility and Sterility, Vol. 79, suppl. 1, pp. 754-762, March 2003).

Note: foreign priority is not considered since no certified copies with English translation were filed.

Connell et al. teach a method of claims 18 to evaluate the integrity of chromatin DNA or DNA of sperm cells of an animal (human) comprising

(a) treating a sample containing the sperm, with a DNA denaturing solution (page 756, col. 2, line 1-5 of paragraph 3 indicating combined alkaline denaturing solution pH 10.0 and lysis solution);

(b) single step treatment of the sample in solution obtained in step a) with a lysis solution (lysis solution with Triton X-100) to extract nuclear proteins of the sperm cells, wherein the lysis solution does not comprise protein denaturing detergents see (page 756, col. 2, line 1-5 of paragraph 3);

(c) evaluating the integrity of the chromatin/DNA of the sperm cells based on measurement of halo of the size of the sperm cells (see page 756, col. 2, paragraph 5).

With regard to claims 20-21, Connell et al. teach that the lysis solution comprises non-ionic non protein detergent as Triton X-100 (see page 756, col. 2, line 1-5 of paragraph 3).

With regard to claims 22-23, Connell et al. teach that the lysis solution comprises sodium chloride between 1 to 3M, DTT between 0.001-2M, Tris between 0.001M to 2m and Triton-X between 0.1% to 3% (see page 756, col. 2, line 1-7 of paragraph 3).

With regard to claim 27, et al. teach that after the step a) and b) there is a staining step (see page 757, col. 1, line 1-3);

With regard to claim 28, Connell et al. teach that said staining solution comprises wright stain (see page 755, col. 2, paragraph 3).

With regard to claim 29-30, Connell et al. teach that the sample containing the sperm is included in a medium similar to a suspension and said medium includes agarose microgel (see page 756, col. 2, paragraph 2). Accordingly the claims are anticipated.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637